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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/656,409	09/06/2000	Scott S. Campbell	19603/1656	9516
7590	12/02/2003		EXAMINER	
Gunnar G Leinberg Esq Nixon Peabody LLP Clinton Square P O Box 31051 Rochester, NY 14603			MATTHEWS, WILLIAM H	
			ART UNIT	PAPER NUMBER
			3738	
DATE MAILED: 12/02/2003				

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)
	09/656,409	CAMPBELL ET AL.
	Examiner William H. Matthews (Howie)	Art Unit 3738

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) Responsive to communication(s) filed on 27 October 2003.
- 2a) This action is FINAL. 2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) Claim(s) 53-57 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) Claim(s) _____ is/are allowed.
- 6) Claim(s) 53-57 is/are rejected.
- 7) Claim(s) _____ is/are objected to.
- 8) Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on _____ is/are: a) accepted or b) objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. §§ 119 and 120

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 a) All b) Some * c) None of:
 1. Certified copies of the priority documents have been received.
 2. Certified copies of the priority documents have been received in Application No. _____.
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 13) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.
 a) The translation of the foreign language provisional application has been received.
- 14) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

Attachment(s)

- 1) Notice of References Cited (PTO-892) 4) Interview Summary (PTO-413) Paper No(s). _____.
 2) Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) Notice of Informal Patent Application (PTO-152)
 3) Information Disclosure Statement(s) (PTO-1449) Paper No(s) 16. 6) Other: _____

DETAILED ACTION

Information Disclosure Statement

1. The information disclosure statement filed 10-27-03 fails to comply with 37 CFR 1.98(a)(2), which requires a legible copy of each U.S. and foreign patent; each publication or that portion which caused it to be listed; and all other information or that portion which caused it to be listed. It has been placed in the application file, but the information referred to therein has not been considered. The US Patent references have been considered, but not the Foreign Patent Documents or Other Documents. Examiner requests Applicant to submit copies in response to this Office Action.

Claim Rejections - 35 USC § 101

2. 35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

3. Claims 53-57 are rejected under 35 U.S.C. 101 because the claimed invention is not supported by either a specific and substantial asserted utility or a well established utility.

Claims 53-57 are directed to a method of resetting a human circadian clock by exposing a non-ocular region, but not a substantially ocular region to non-solar photic stimulation. "Absence of Circadian Phase Resetting in response to Bright Light Behind the Knees" by Wright Jr. and Czeisler (Science Magazine 297 (5581):571) discloses a specific attempt to replicate the current invention without success. Furthermore, Wright et al. suggests ocular exposure to light is required for resetting the circadian clock.

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Claims 53-57 are rejected under 35 U.S.C. 112, first paragraph. Specifically, since the claimed invention is not supported by either a specific and substantial asserted utility or a well established utility for the reasons set forth above, one skilled in the art clearly would not know how to use the claimed invention.

Claim Rejections - 35 USC § 102

4. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

5. Claims 53-57 are rejected under 35 U.S.C. 102(b) as being anticipated by Czeisler et al. US PN 5,304,212.

Regarding claims 53-57, Czeisler et al. discloses a system comprising a temperature measuring system (lines 30-54 of column 13) and non-solar photic stimulation generating system (lines 20-65 of column 62) that activates upon an assessed time to adjust the circadian cycle of a human. Line 59 of column 39 to line 9 of column 40, figure 11, and figure 15b describe various times when light exposure begins. The assessed time of the minimum body temperature is shown in figure 11 as ECP_{min}. Regarding claims 54-57, figure 11 shows the time of exposure occurring between about 6 hours before to 6 hours after the assessed time, ECP_{min}. Lines 6-8 of column 40 further describe a second pulse of 3500-6000 lux light beginning five hours after the initial pulse.

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With regard to the positioning of the non-solar photic stimulation device, Figure 39B and lines 54 of col. 64 through line 25 of col. 65 disclose positioning such that non-ocular regions are exposed.

6. Claims 53,54,56 are rejected under 35 U.S.C. 102(b) as being anticipated by Czeisler et al. "Suppression of Melatonin Secretion in some Blind Patients by Exposure to Bright Light" (New England Journal of Medicine, Vol. 332:6-11 January 5, 1995).

Czeisler et al. discloses a method of resetting a human circadian clock by exposing non-ocular regions with non-solar light. A temperature measuring system is disclosed to assess the minimum temperature and exposure times were at 22-23 hrs after the initial temperature minimum, which would also be before the subsequent assessed minimum.

Claim Rejections - 35 USC § 103

7. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

8. Claims 53-57 are rejected under 35 U.S.C. 103(a) as being unpatentable over Vreman et al. US PN 6,350,275 in view of Czeisler et al. US PN 5,304,212.

Vreman et al. discloses in figures 3,4, and 7 and lines 39 of col. 5 through line 13 of col. 6 a method of resetting human circadian clocks by exposing non-ocular regions with non-solar photic stimulation. Vreman et al. lacks the express written disclosure of

utilizing a temperature measuring system to apply light about six hours before or after the assessed time. Czeisler et al. teaches in line 59 of col. 39 to line 9 of col. 40, figure 11, and figure 15b that it is well known to use temperature measuring systems to apply light according to an assessed time related to temperature minimums in order to reset the circadian clock. The assessed time of the minimum body temperature is shown in figure 11 as ECP_{min}. Regarding claims 54-57, figure 11 shows the time of exposure occurring between about 6 hours before to 6 hours after the assessed time, ECP_{min}. Lines 6-8 of column 40 further describe a second pulse of 3500-6000 lux light beginning five hours after the initial pulse.

Therefore it would have been obvious to one of ordinary skill in the art at the time of the invention to have modified the device disclosed by Vreman et al. by including a temperature measuring system to apply light about six hours before or after the assessed time, as taught by Czeisler et al. in order to reset the circadian clock of a human.

9. Claims 55 and 57 are rejected under 35 U.S.C. 103(a) as being unpatentable over Czeisler et al. "Suppression of Melatonin Secretion in some Blind Patients by Exposure to Bright Light" (New England Journal of Medicine, Vol. 332:6-11 January 5, 1995).as applied to claims 53, 54, and 56 above, and in further view of Czeisler et al. US PN 5,304,212.

Czeisler et al. "Suppression of Melatonin Secretion in some Blind Patients by Exposure to Bright Light" discloses a method of resetting human circadian clocks by exposing non-ocular regions with non-solar photic stimulation dependent upon a

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temperature measuring system which determines minimum temperature, but Czeisler et al. "Suppression of Melatonin Secretion in some Blind Patients by Exposure to Bright Light" lacks the express written disclosure of applying light about six hours before or after the assessed time. Czeisler et al. '212 teaches in line 59 of col. 39 to line 9 of col. 40, figure 11, and figure 15b that it is well known to apply light according to an assessed time related to temperature minimums in order to reset the circadian clock. The assessed time of the minimum body temperature is shown in figure 11 as ECP_{min}. Regarding claims 54-57, figure 11 shows the time of exposure occurring between about 6 hours before to 6 hours after the assessed time, ECP_{min}. Lines 6-8 of column 40 further describe a second pulse of 3500-6000 lux light beginning five hours after the initial pulse.

Therefore it would have been obvious to one of ordinary skill in the art at the time of the invention to have modified the device disclosed by Czeisler et al. "Suppression of Melatonin Secretion in some Blind Patients by Exposure to Bright Light" by applying light about six hours before or after the assessed time, as taught by Czeisler et al. '212 in order to reset the circadian clock of a human.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to William H. Matthews (Howie) whose telephone number is 703-305-0316. The examiner can normally be reached on Monday-Friday 10-6:30PM.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Corrine M. McDermott can be reached on 703-308-2111. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0858.

WH
WHM
November 30, 2003

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